

**Notice of Allowability**

Application No.

10/627,399

Applicant(s)

REDDY ET AL

Examiner

Robert Shiao

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1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to October 17, 2005.
2. ☒ The allowed claim(s) is/are 3-18, now are 1-16.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                      |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                              |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance             |
|   | 9. <input type="checkbox"/> Other _____  |

### **DETAILED ACTION**

1. This application claims benefit of the foreign application, INDIA 594/MAS/2002 with a filing date 08/12/1999. A certified copy of the priority document filed on July 20, 2005, is acknowledged.
2. Amendment of claims 1-2 in the amendment filed October 17, 2005, is acknowledged. Claims 1-18 are pending in the application.

### ***Responses to Amendment/Arguments***

3. Applicant's arguments regarding rejection of claim 2 under 35 U.S.C. 112, second paragraph, filed on October 17, 2005, have been fully considered but they are not persuasive. The instant X-ray powder diffraction data has not been incorporated, therefore, rejection of claim 2 under 35 U.S.C. 112, second paragraph, is maintained.
4. Applicant's arguments regarding rejection of claims 1-2 under 35 U.S.C. 103(a), filed on October 17, 2005, have been fully considered but they are not persuasive. A number of case laws cited by applicants, i.e., *In re O'Farrell*, 853 F. 2d F. 894, 7 USPQ2d 1673 (Fed. Cir 1988) or *Ex parte Obukowicz*, 27 USPQ 2d 1063 (Bd.Pat. App. &Interf.1992), are also acknowledged.

Applicants assert that it would not be obvious to try to make a polymorphic form of instant sumatriptan succinate. However, it is noted that it has long been the practice in the chemical and pharmaceutical arts to produce compounds in the form of amorphous or crystals to secure a pure and stable product. There is no patentable distinction in the concept of a chemical compound in amorphous or crystalline form over

the same compound, i.e., Winterborn et al. compounds, see *In re Weijlard*, 69 U.S.P.Q. 86, 87 (C.C.P.A. 1946). Further, changing the form, purity or other characteristic of an old product does not render the novel form patentable where the difference in form, purity or characteristic was inherent in or rendered obvious by the prior art, see *In re Cofer*, 148 U.S.P.Q. 268 (CCPA 1966).

Therefore, rejection of claims 1-2 under 35 U.S.C. 103(a) over Winterborn et al. EP 0496307 A1 in view of Crisp et al. US 4,820,833 or Cheronis's publication, "Semimicro Experimental Organic Chemistry", 1958, Chapter 5, is maintained.

#### ***EXAMINER'S AMENDMENT***

5. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee. Authorization for this examiner's amendment was given in a telephone interview with Robert A. Franks on November 10, 2005. The application has been amended as follows:

Delete claims **1-2**

#### ***Reasons for Allowance***

6. The following is an examiner's statement of reasons for allowance:

Claims 3-18 are neither anticipated nor rendered obvious over the art of record, and therefore are allowable. This invention relates to amorphous form of 3-[2-

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(dimethylamino) ethyl]-N-methyl-1H-indole-5-methane sulfonamide succinate. The closest reference is Craig et al. US 5,554,639, discloses medicaments. The difference between Craig et al. and instant claims is that the instant processes of making have not been disclosed in Craig et al. Suggestion for modification of above record to obtain the instant claimed processes has not been found. Claims 3-18 are allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

### ***Conclusions***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707.

The examiner can normally be reached on 8:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private

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November 14, 2005